

U.S. Serial No. 09/813,352
Amendment dated 17 March 2004
Reply to Office Action mailed 17 December 2003

REMARKS

Claims 1-24 and 32-36 have been canceled as being drawn to a non-elected invention without prejudice to filing a divisional application.

Claim 37 has been canceled in view of the amendment of claim 25.

Claims 26, 27 and 38 have been amended to depend from claim 25 in view of the cancellation of claim 37.

New claims 39-44 have been added. Claims 39-44 are identical to claims 28 and 29 except for their dependencies.

It is submitted that none of these amendments constitute new matter, and their entry is requested.

The Examiner rejected claim 25 and its dependent claims under 35 U.S.C. § 112, first paragraph for lack of written description. The Examiner contends that the term "heterologous promoter" is new matter. Applicants do not agree with the Examiner. It is true that the term "heterologous promoter" is not used *per se* in the specification. However, this term is described and supported by the examples of promoters provided in the specification. Specifically, the specification describes constitutive and activatable promoters. The cauliflower mosaic virus 35S promoter is given as an example of a constitutive promoter and three references are provided that describe activatable promoters, i.e., inducible and derepressible promoters. See for example, page 15, lines 11-14 and page 17, lines 19-20. Each of these promoters is a heterologous promoter. Nevertheless, in order to advance the prosecution of this application, Applicants have amended claim 25 to set forth the types of promoters described in the application and as previously found in claim 37. It is submitted that the amendment of claim 25 obviates this rejection, and its withdrawal is requested.

The Examiner rejected claims 25-29, 37 and 38 under 35 U.S.C. § 112, first paragraph, for lack of enablement. The Examiner contends that the specification only enables a seed, seedling or plant containing a polynucleotide comprising a constitutive promoter and a nucleic acid encoding ABI5 which expresses ABI5. The Examiner further contends that the specification does not enable

a seed, seedling or plant which does not express ABI5 or in which the promoter is a nonconstitutive promoter, an inducible promoter or a derepressible promoter. It is submitted that the Examiner is in error in this rejection and has not provided any sound scientific basis for doubting the objective enablement of the present application.

First, Applicants have amended claim 25 to recite constitutive, inducible and derepressible promoters. This amendment removes nonconstitutive promoters from the scope of the claim and any reasons for lack of enablement on the basis of this term have been obviated.

Second, Applicants submit that the specification fully describes how to make seeds, seedlings or plants which contain a polynucleotide comprising an inducible or derepressible promoter operatively linked to a nucleic acid encoding ABI5, a fact which the Examiner concedes. Such a seed, seedling or plant would not express ABI5 unless activated as would be known to a skilled artisan reading the specification. That is, the seed, seedling or plant would not express ABI5 until the promoter was activated. If the promoter was never activated, the seed, seedling or plant would never express ABI5. Thus, the specification teaches how to make a seed, seedling or plant which does not express ABI5. Applicants further submit that the specification teaches how to use such a seed, seedling or plant. Such a seed, seedling or plant in which ABI5 is not expressed is used when it is not desired to delay germination, inhibit growth of germinated embryo or render hypersensitive to ABA or when there are no conditions of drought or high salt. This use of a seed, seedling or plant not expressing ABI5 is the converse of the use of a seed, seedling or plant expressing ABI5.

Third, Applicants submit that the specification fully enables when in plant development the inducible or derepressible promoter should be activated to produce the desired effect. For example, if it is desired to delay germination, ABI5 is expressed in the seed prior to germination. See for example, original claim 1. The activatable promoter is activated by applying the activator to the seed. If it is desired to inhibit growth of the germinated embryo, the promoter is activated by applying the activator to the germinated embryo, i.e., seedling. See for example, original claim 4. If it is desired to make a seed, seedling or plant hypersensitive to ABA, the promoter is activated by

applying the activator to the seed, seedling or plant when it is desired to induce the hypersensitivity. See for example, original claim 13. The application of an activator to a seed, seedling or plant to activate a promoter is described at page 17, lines 14-17, is well known in the art and is thus fully enabling. The expression of the gene could occur in any tissue as is the case when a constitutive promoter is used.

Fourth, Applicants submit that the Examiner has not set forth an analysis of the *Wands* factors as required by the Patent Office's guidelines for enablement rejections. Thus, the Examiner has not presented a *prima facie* case of lack of enablement.

Fifth, the "examiner has the initial burden to establish a reasonable basis to question the enablement provided for the **claimed** invention." MPEP2164.04, *citing In re Wright*, 999 F.2d 1557, 1562, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir.1993) (emphasis added). In *Wright*, the Court made clear that the PTO has the burden of providing a reasonable explanation of why the specification does not enable. Furthermore, there must be some reason to doubt the objective truth of the statements in the specification. M.P.E.P. § 2164.04; *In re Marzocchi*, 169 USPQ 367 (CCPA 1973). Applicants submit that the Examiner has not provided acceptable evidence to doubt the objective enablement of the specification and to support her contention that the specification is not enabling. As the Court said in *Marzocchi*,

[I]t is incumbent upon the Patent Office, whenever a rejection on this basis [i.e. doubt of the objective truth of statements in the specification] is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. Otherwise, there would be no need for the applicant to go through the trouble and expense for supporting his presumptively accurate disclosure.


169 U.S.P.Q. at 370. In the absence of suitable evidence, the Examiner has not met her burden of establishing non-enablement.

For all of the above reasons, Applicants submit that the specification fully enables the claimed invention. Withdrawal of this rejection is requested.

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In view of the above amendments and remarks, it is submitted that the present claims satisfy the requirements of the patent statutes and are patentable over the prior art. Reconsideration and early notice of allowance are requested. The Examiner is invited to telephone the undersigned in order to expedite prosecution of the present application.

Respectfully submitted,
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